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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,824	01/11/2002	Michael Donald Farley	FA-004	4385

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EXAMINER	
COE, SUSAN D	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 11/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/045,824	FARLEY, MICHAEL DONALD	
	Examiner	Art Unit	
	Susan D. Coe	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-10 are currently pending.

Claim Objections

2. Claims 1-10 are objected to because of the following informalities:

In claims 1, 4 and 7-10, "Clorius" and "Colorius" are misspellings of "Coriolus" and "Diindolymethane" is a misspelling of "Diindolylmethane."

In claims 1, 8, and 10, "selinium" is a misspelling of "selenium."

In claim 2, "myricertin" is a misspelling of "myricetin."

In claims 3 and 6-10, "Phosphitidyl" is a misspelling of "Phosphatidyl."

In claims 4, 8 and 10, "polysecride" and "polysacride" are misspellings of "polysaccharide."

In claim 9, the notation of "3,3' " is not in the correct form; it is incorrectly noted as "3.3' ".

Claims 4 and 7-10 do not end in a period.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition consisting of the claimed ingredients, does not reasonably provide enablement for a composition consisting of the claimed ingredients "for a human body's natural immune function." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's claims are directed to a composition "for a human body's natural immune function." The meaning of the phrase is unclear, does this mean that the composition is intended to increase the natural immune function? Applicant's specification indicates that this is the intended use; however, as drafted, the claims are very unclear on this point. In addition, applicant's specification does not actually support this use of the claimed composition. Applicant's specification does not provide any evidence to show that the claimed composition is able to support or enhance the immune system in any way. It is known in the art that the action of pharmaceuticals is very unpredictable. Thus, since the specification does not provide clear support for this use, a person of ordinary skill in the art would be forced to experiment unduly in order to determine if the invention functions as claimed. Therefore, the claims are not considered enabled for the intended use of the composition.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 1, 4, and 7-10 are indefinite because it is unclear what is meant by "a human body's natural immune function." This point is discussed above in paragraph 3.

5. Claims 1, 7, and 9 are indefinite because the correlation between the milliliters of apigenin and the total unit dose amount is unclear. Does the use of milliliters to indicate the amount of apigenin indicate that the entire composition is in liquid form?

6. Claim 1 is indefinite because item (i) is unclear. Does this item mean that the selenium methionine is a source of the trace mineral selenium?

7. Claims 2, 3, 5, and 6 are indefinite because they improperly change the scope of the parent claims. The parent claims "consist of" the claimed ingredients. This transitional phrase does not allow for the inclusion of any additional unrecited elements. Claims 2, 3, 5, and 6 state that these parent claims "also include" additional ingredients. This is improper.

8. Claim 4, item (i), claim 8, item (j) and claim 10, item (j) are indefinite because it is unclear what the notation enclosed in the parentheses is indicating. Is this the concentration of selenium methionine used? In addition, the use of parentheses in this case is indefinite because it is unclear if the enclosed limitation is a required limitation of the claim.

9. Claims 7 and 9 are indefinite because item (j) is unclear. It states:--

Trace mineral selenium - L - 10 to 60 mgs

L-Selenium methionine (5000 mcg/gr) --

What does the first "L" refer to? In addition, are two types of selenium required? Furthermore, it is unclear what the notation enclosed in the parentheses is indicating. Is this the concentration of selenium methionine used? In addition, the use of parentheses in this case is indefinite because it is unclear if the enclosed limitation is a required limitation of the claim.

Conclusion

10. No claims are allowed. However, the claims are considered free of the prior art and would be considered allowable if amended to delete "for a human body's natural immune function" and to correct the above noted claims objections and 112 2nd issues.

The closest prior art is US Pat. No. 6,544,564 to the same inventor. The claims of the patent contain similar ingredients. However, there is considered to be no motivation to alter the ingredients of the claims of the patent to conflict with the current claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 9:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding can be directed to the receptionist whose telephone number is (571) 272-1600.

Susan D. Coe
11-2-05

Susan D. Coe
Primary Examiner
Art Unit 1655